

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEE
KNOXVILLE DIVISION**

STATE OF TENNESSEE, *et al.*,

Plaintiffs,

v.

No. 3:25-cv-25

U.S. DEPARTMENT OF HEALTH AND
HUMAN SERVICES, *et al.*,

Defendants.

DEFENDANTS' REPLY IN SUPPORT OF THEIR MOTION TO DISMISS

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INTRODUCTION

As Defendants' motion to dismiss explains, this case is precisely the type that Article III is intended to "screen[] out." *See FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 381 (2024). Although the States undoubtedly oppose the rule they seek to challenge, *HIPAA Privacy Rule to Support Reproductive Health Care Privacy*, 89 Fed. Reg. 32976 (Apr. 26, 2024) ("Rule"), there is no indication in the complaint that the Rule *itself* is injuring them in any cognizable way—a fundamental condition of Article III standing. The States' counterarguments cannot cure this failure. Contrary to what they contend, the States do not have standing based purely on the fact that the Rule regulates them. And though the States insist that the Rule's requirements thwart their investigations and impose compliance costs, they point to no specific, concrete *facts* in the complaint that support those allegations. The absence of any well-pleaded facts showing a cognizable injury attributable to the Rule is dispositive of the parties' cross-motions: This Court lacks jurisdiction and should dismiss this case accordingly.

ARGUMENT

In their opposition brief, *see* Pls.' Combined Resp. to Defs.' MTD & Reply in Supp. of Their Mot. for Summ. J. & Prelim. Relief ("Opp."), ECF No. 88, the States insist they have done enough to plausibly allege Article III standing to challenge the Rule. But their arguments on this score miss the mark. Although Defendants' prior briefing already rebuts most of these arguments, *see* Defs.' Opp. to Pls.' Mot. for Summ. J. & Prelim. Relief & Cross-MTD ("Mot.") at 8–12, ECF No. 65, a few points warrant a response.

First, the States appear to suggest that they need not show an actual injury attributable to the Rule to establish Article III standing, because it is enough that they are subject to the Rule's requirements. *See, e.g.*, Opp. at 3 ("Because they are directly regulated by the Final Rule ... Plaintiff States' standing is 'self-evident.'") (citation omitted)). But the States' own selection of cases contradicts this claim. The line of authority that they invoke—originating with *Lujan v. Defenders of Wildlife*, 504

U.S. 555 (1992)—simply explains that standing is typically easier to establish where a regulation requires the plaintiff, rather than someone else, to act. *See, e.g., All for Hippocratic Med.*, 602 U.S. at 382; *Carman v. Yellen*, 112 F.4th 386, 399 (6th Cir. 2024). But a plaintiff that is regulated by a challenged action, like any other, must still establish a cognizable injury resulting from that action and redressable by a favorable judgment. *Carman*, 112 F.4th at 399–400; *accord Lujan*, 504 U.S. at 561–62. These cases thus do not support the proposition that a regulated plaintiff has standing *ipso facto*. Indeed, it “would fly in the face of Article III’s injury-in-fact requirement” to hold, as the States seem to contend, that a plaintiff has standing to challenge a “regulation in the abstract,” “apart from any concrete application that threatens imminent harm” to its interests. *Summers v. Earth Island Inst.*, 555 U.S. 488, 494 (2009). And while the States cite a few out-of-circuit and district court cases that seemingly share their lax view of standing, those cases cannot be squared with binding precedent like *Lujan* and *Carman*, which acknowledge that a plaintiff that is “an object of” a challenged action still must show that the “action … has caused” it a cognizable “injury.” *Lujan*, 504 U.S. at 561–62; *accord Carman*, 112 F.4th at 399–400; *see also, e.g., Littman v. U.S. Dep’t of Labor*, 2025 WL 763583, at *5 (M.D. Tenn. Mar. 11, 2025) (“While ‘objects’ of a regulation ordinarily will have an easier time satisfying the three standing requirements, that does not mean ‘objects’ are absolved from establishing [those requirements] altogether.” (citing *Lujan*, 504 U.S. at 560; *Carman*, 112 F.4th at 399–400)); *Lower E. Side People’s Fed. Credit Union v. Trump*, 289 F. Supp. 3d 568, 579 (S.D.N.Y. 2018) (“[T]he mere fact that Plaintiff is regulated by the CFPB does not confer standing to bring this suit. Plaintiff must instead allege a concrete and particularized injury caused by CFPB actions....”).¹

¹ *West Virginia v. EPA*, 597 U.S. 697 (2022), is not to the contrary. There, the Supreme Court explained that the Clean Power Plan (“CPP”), if it came back into legal effect as a result of a lower court’s decision, would “injure” the state plaintiffs that were “the object of” its requirement that they more stringently regulate power plan emissions within their borders.” *Id.* at 718–19 (quoting *Lujan*, 504 U.S. at 561–62). The fact that the Court did not expound on what those precise injuries were is unsurprising given that the government *conceded* that the state plaintiffs would have standing under

Insofar as the States contend that simply complying with the Rule’s attestation requirement injures them in an Article III sense, *see* Opp. at 4–6, that new theory of harm is nowhere featured in their complaint. While the complaint mentions the attestation requirement, the harms the States allege are merely twofold: that the Rule “impedes” their ability to obtain information through state-run investigations and requires administrative costs to comply. *See* Compl. ¶¶ 90–115. The States cannot shoehorn new allegations of harm into their complaint through briefing on Defendants’ motion to dismiss. *See, e.g., Calderwood v. United States*, 623 F. Supp. 3d 1260, 1278–79 (N.D. Ala. 2022) (finding that “new injuries” raised “only in briefing” and “found nowhere in the[] complaint” “cannot support standing”); *see also Williamson v. Cocke Cnty. HMA, LLC*, 2019 WL 13197853, at *8 (E.D. Tenn. June 27, 2019) (rejecting plaintiffs’ attempt to “add substance” to their complaint “through briefing”); *Forrester v. Am. Sec. & Prot. Serv. LLC*, 2022 WL 1514905, at *2 (6th Cir. May 13, 2022) (same). The States nowhere explain how they are meaningfully burdened by completing an attestation with readily available information, *see* Mot. at 11, and their belated assertion that doing so requires a “complex, high-stakes legal analysis,” *see* Opp. at 7, finds no support in the complaint, which cites no instance where such an analysis would have been necessary.

Second, as Defendants explained, *see* Mot. at 10–11, the States failed to allege sufficient facts that would allow this Court to meaningfully assess whether the Rule *itself* is actually impeding any state’s ability to investigate violations of state law.² *See Mackinac Ctr. for Pub. Policy v. Cardona*, 102 F.4th 343, 352 (6th Cir. 2024) (requiring “specific, concrete facts” to plausibly allege standing); *Spokeo, Inc.*

those circumstances, *see* Br. for the Fed. Resps. at 21–22, *West Virginia v. EPA*, Nos. 20-1530, 20-1531, 20-1778, 20-1780 (U.S. Jan. 18, 2022) (“Petitioners had a concrete stake … when vacatur of the CPP Repeal Rule might have caused the CPP to take effect.”), and that the principal justiciability issue before the Court was one of mootness, not standing, *West Virginia*, 597 U.S. at 719–20.

² The States’ assertion that Defendants have “conced[ed] that the complaint details multiple investigations the [Rule’s] attestation requirement has hampered,” *see* Opp. at 6, is more than a little puzzling, given that the insufficiency of the complaint’s allegations on that score is a principal basis of Defendants’ motion, *see* Mot. at 10–11.

v. Robins, 578 U.S. 330, 338 (2016) (requiring a plaintiff to “clearly allege facts demonstrating each element” of standing). The States resist that conclusion by plucking out two examples of investigations they claim the Rule has thwarted. *See Opp.* at 6 (citing Compl. ¶¶ 107, 110). But both examples prove Defendants’ point. One involves a health care provider that allegedly refused to comply with a request for information from a state agency that had provided an attestation. *See Compl.* ¶ 110. But as Defendants explained, *see Mot.* at 10 n.1, the complaint never explains *why* the provider refused to comply or *how*, if at all, the Rule hindered the state agency’s ability to obtain the requested information or to pursue its investigation. Without more, there’s no basis for the Court to conclude that, taking the complaint’s well-pleaded facts as true, the state’s investigation has actually been thwarted, much less that the Rule itself was the cause. *See Ass’n of Am. Physicians & Surgeons v. FDA*, 13 F.4th 531, 546 (6th Cir. 2021) (rejecting standing theory that required this type of “guesswork”). The States’ other example involves Tennessee’s alleged inability to obtain certain information through civil discovery without an attestation. *See Compl.* ¶ 107. But that allegation also leaves one guessing whether the state provided an attestation; and if not, whether it was nonetheless able to obtain the information. *See Mot.* at 10. Again, absent more concrete allegations, the complaint leaves unclear whether the state was actually unable to obtain the information it sought, and if so, whether that was fairly traceable to the Rule or to Tennessee’s own actions. *See Bucholz v. Meyer Njus Tanick, PA*, 946 F.3d 855, 866–67 (6th Cir. 2020) (“A self-inflicted injury … is not traceable to anyone but the plaintiff.”).³

Third, as Defendants explained, *see Mot.* at 11, the States’ threadbare allegation that complying with the Rule “produces administrative costs,” *see Compl.* ¶ 99, lacks the factual support necessary to

³ The States cannot seek to buttress their complaint with extraneous declarations submitted in support of their motion for summary judgment, *contra Opp.* at 7 n.5, given that Defendants have brought a facial challenge to the Court’s jurisdiction under Federal Rule of Civil Procedure 12(b)(1). *See L.C. v. United States*, 83 F.4th 534, 542 (6th Cir. 2023) (explaining that a “facial” attack under Rule 12(b)(1) accepts the truth of the plaintiff’s well-pleaded allegations but asserts that they are insufficient on their face to invoke federal jurisdiction).

plausibly allege Article III standing. *See Mackinac Ctr.*, 102 F.4th at 352; *see also, e.g., Hekel v. Hunter Warfield, Inc.*, 118 F.4th 938, 943 (8th Cir. 2024) (rejecting a standing theory that rested on conclusory allegations of economic injury where the complaint identified no “*specific* … expenses” that the defendant’s action “caused” the plaintiff “to incur”). In response, the States never try explain why they failed to provide even a barebones description of the costs they supposedly need to incur to comply with the Rule—which should have been easy to provide when the States filed their complaint if the Rule truly imposed the resource burdens they allege. Instead, the States misdirect by arguing that they need not describe their alleged compliance costs with “exacting” or “granular detail.” *See Opp.* at 7–8. But that misses the point entirely: the States have provided *no* detail whatsoever, relying instead on highly generalized assertions unaccompanied by supporting facts. *See, e.g., Compl. ¶ 115* (“[C]ompliance has … imposed financial, logistical, and personnel burdens on state agencies to ensure effective disclosure requirements.”). The States compound their error by further arguing that they need not allege that the Rule requires them to incur costs above and beyond whatever costs the States already incur when making requests for information consistent with other applicable requirements, *see Opp.* at 8, the latter of which are not traceable to the Rule and thus cannot confer standing, *see All. for Hippocratic Med.*, 602 U.S. at 382 (explaining that Article III standing requires “causation” between the challenged action and the alleged injury). And as already explained, *see Mot.* at 14, the States cannot show a *particularized* injury based on the Rule’s assumption that, generally, covered entities would need to develop new or modified policies or procedures following the Rule’s promulgation. *See, e.g., Crawford v. U.S. Dep’t of Treasury*, 868 F.3d 438, 453 (6th Cir. 2017) (explaining that Article III requires “that the plaintiff *personally* have suffered some actual or threatened injury” (cleaned up)).

CONCLUSION

The Court should dismiss this case for lack of jurisdiction.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

On April 21, 2025, I electronically submitted the foregoing document with the Clerk of Court for the U.S. District Court, Eastern District of Tennessee, using the Court's electronic case filing system. I hereby certify that I have served all parties electronically or by another manner authorized by Federal Rule of Civil Procedure 5(b)(2).

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